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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,691	11/26/2003	Karl Reinitz	0121	6148
32366 7590 04/27/2007 BRUCE E. WEIR 12 SPARROW VALLEY COURT MONTGOMERY VILLAGE, MD 20886-1265			EXAMINER LANG, AMY T	
			ART UNIT 3731	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE 3 MONTHS		MAIL DATE 04/27/2007	DELIVERY MODE PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/721,691

Applicant(s)

REINITZ, KARL

Examiner

Amy T. Lang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

All rejections not included in this office action have been withdrawn in light of applicant's amendments filed 04/03/2007.

Response to Arguments

Applicant's arguments filed 04/03/2007 have been fully considered but they are not persuasive.

1. Specifically, applicant argues (A) that "Applicant is unable to locate any reference or implicit, by Hill et al. that the shuttle is in any way intended to mask the tip of the needle to avoid accidental tissue penetration," with regard to claims 1, 2, 3, 6, 7, 10, and 11.

With respect to argument (A), claims 1, 2, 3, 6, 7, 10, and 11 do not claim wherein the moveable arm masks the tip of the needle to avoid accidental tissue penetration.

2. Specifically, applicant argues (B) that Hill et al, with regard to claims 1, 2, 3, 6, 7, 10, and 11 does not disclose a moveable arm as claimed.

With respect to argument (B), Hill et al. discloses a shuttle (36) comprising a proximal and distal end. The proximal end is moveable attached to the body (32) of the

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device and the distal end contacts a portion of the needle tip (31) (Figures 4 and 5).

Therefore, it is the examiner's position that the shuttle of Hill et al. clearly overlaps the instantly claimed moveable arm.

3. Specifically, applicant argues (C) that specific elements of Gimpelson, with regard to claim 19, do not the specific elements in the instant claims.

With respect to argument (C), the instant claim 19 broadly discloses a device comprising a suturing means, a protection means, and a means for engaging the projection means with the suturing means. Gimpelson, as shown in Figures 3D-3I discloses a device comprising a suturing means (10), a protection means (44), and a means for engaging the projections means with the suturing means (Figures 3G and 3H).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites the tapered portion of the needle having a

center line comprising the centroids of adjacent selected planar cross-sections of the tapered portions. However, it is the examiner's position that this limitation is not supported by the specification.

6. Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 10 and 11 recite wherein the depressions are in locations where they may accept an operator's fingers while the operator is placing sutures. However, it is the examiner's position that this limitation is not supported by the specification.

7. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 12 recites wherein the apparatus is "optimized" for left-handed use. However, it is the examiner's position that the limitation "optimized" is not supported by the specification.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 3, 6, 7, 10, 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Hill et al. (US Patent 7,122,040). Hill et al. disclose a suturing apparatus comprising a body, a needle having a proximal and distal end, the distal end of the needle having a tip capable of penetrating tissue, a moveable arm, and a moveable arm actuator that contacts the tip of the suture needle (see figure 10). The moveable arm can be actuated to a closed position or an open position. Hill et al. disclose a needle in figure 7B with a J-shape or hook shape. The distal end of the needle has a passage to hold the suture material. The moveable arm actuator comprises a compression member, disclosed as a spring in col. 4, lines 10-12, which acts to move the arm to a closed or open position.

Regarding claims 10 and 11, Hill et al. further disclose a first depression and a second depression, shown in figure 6, disposed on the opposite sides of the body and underside of the body. It is the examiner's position that the depressions are located so that an operator may place his hands upon them while placing sutures.

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10. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Gimpelson (US Patent 5,336,239). Gimpelson discloses a suture needle comprising a suture passage, a member that covers the needle tip to protect the suture means, and a means for engaging the suture means. See figures 3D-3I.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 4, 5, 8, 9, 13, 14, 16, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (US Patent 7,122,040), in view of Kirk III, et al. (US Patent 5,151,089), hereinafter "Kirk". Hill et al. disclose a suturing apparatus with a moveable arm, moveable arm actuator, and a needle with a hook or J-shape, and a first depression and a second depression, shown in figure 6, disposed on the opposite sides of the body and underside of the body. However, Hill et al. lack the moveable arm pivotally mounted about the body. Hill et al. are also silent as to the material composition of the device. Kirk discloses a body, a needle, and a retractable pivotable arm (reference 11, figure 7) that acts as a protective sheath for covering the tip of the needle to avoid accidental penetration of tissue.

Regarding claims 8 and 14, Kirk discloses the device composed of a material that will permit sterilization (col. 5, lines 58-60). It is well known in the art to

manufacture surgical instruments from compositions that are capable of tolerating the temperatures of autoclave sterilization.

Regarding claims 9 and 16, Kirk discloses a handle attached to opposite sides of the body. This handle could presumably be used by one hand.

Therefore, it would have been obvious to one of ordinary skill in the art to provide the device of Hill et al. with the features taught by Kirk of a protective arm, a handle attached to opposite sides of the body, and an instrument that will tolerate autoclave sterilization.

13. Claims 12 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (US Patent 7,122,040) in view of Kirk (US Patent 5,151,089), and in further view of Hasson (US Patent 5,628,757). Hill et al. disclose a trigger like handle, with grooves shown to provide a better grip, and Kirk discloses a simplified handle disposed on opposite sides of the body. The invention of Hasson combines the features of the handles of Hill et al. and Kirk, and teaches two members (Figure 3, 104 and 106), each disposed on opposite sides of the body. The second member (106) teaches depressions on the opposite sides located on the underside of the handle (col. 7, lines 5-10). Hasson teaches this design facilitates ambidextrous gripping of the device, that is, by either the right or left hand (col. 7, lines 5-10). Therefore, it would have been obvious to one of ordinary skill in the art to modify the design of Hill et al. and Kirk with the features of Hasson to enable the device to be easily gripped with only one hand.

Conclusion

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Lang whose telephone number is (571) 272-9057. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/20/2007

Amy T. Lang

ATL


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

4/26/07